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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/583,046

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Keiji Kubo

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03/27/2008

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EXAMINER

CHU, YONG LIANG

ART UNIT

PAPER NUMBER

1626

MAIL DATE

DELIVERY MODE

03/27/2008

PAPER

**Please find below and/or attached an Office communication concerning this application or proceeding.**

The time period for reply, if any, is set in the attached communication.

<b>Office Action Summary</b>	<b>Application No.</b> 10/583,046	<b>Applicant(s)</b> KUBO ET AL.	
	<b>Examiner</b> Yong Chu	<b>Art Unit</b> 1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-30 is/are pending in the application.
- 4a) Of the above claim(s) 12 and 24-29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18 is/are allowed.
- 6) ☒ Claim(s) 1-11, 13-15, 17, 19-23 and 30 is/are rejected.
- 7) ☒ Claim(s) 1-11, 13-17, 19-23 and 30 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- |  |   |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892)            | 4) <input type="checkbox"/> Interview Summary (PTO-413)           |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948)    | Paper No(s)/Mail Date. _____                                      |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>07/27/2006, 09/21/2006, and 10/12/2007</u> .                  | 6) <input type="checkbox"/> Other: _____                          |



## DETAILED ACTION

Claims 1-30 are pending in the instant application.

### *Information Disclosure Statement*

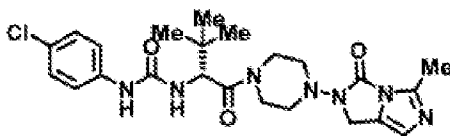
Applicants' Information Disclosure Statements, filed on 07/27/2006, 09/21/2006, and 10/12/2007, have been considered. Please refer to Applicant's copies of the PTO-1449 submitted herewith.

### *Priority*

This application is a 371 of PCT/JP04/18717 filed on 12/15/2004, which claims the benefit of foreign priority of Japan Patent Application 2003-420031, filed on 12/17/2003.

### *Response to Restriction*

Applicants' election with traverse of Group I (claims 1-23 and 30) with elected



species of the compound

as Example 20 on page 120

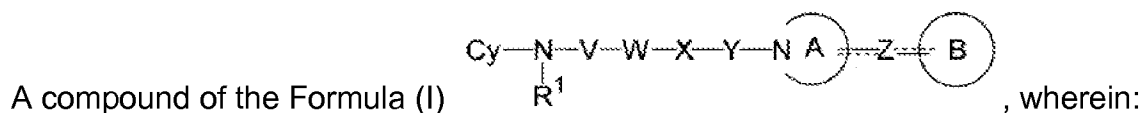
of the specification in the reply filed on 01/14/2008 is acknowledged. Because there is no argument over the fault for traversal, it is considered as without traverse.

### ***Status of the Claims***

Claims 24-29 are withdrawn from further consideration by the Examiner as being drawn to non-elected inventions under 37 CFR 1.142(b) due to the restriction requirement.

### **Elected and Examined Subject Matter**

The scope of the invention of the elected subject matter and the examined subject matter is as follows:



**Cy** is phenyl which may be substituted;

**R<sup>1</sup>** is a hydrogen atom;

**V** is  $-\text{C}(\text{O})-$ ;

**W** is  $-\text{N}(\text{R}^2)-$ , wherein **R<sup>2</sup>** is a hydrogen;

**X** is alkylene which may be substituted;

**Y** is  $-\text{C}(\text{O})-$ ;

**Z** is a bond;

"-----" is a single bond,

**Ring A** is a piperazine ring which may be substituted; and

**Ring B** is a fused nitrogen-containing heterocyclic group which may be substituted.

As a result of the election and the corresponding scope of the invention identified supra, claim 12, and the remaining subject matter of claims 1-11,13-17, 19-23 and 30 are further withdrawn from further consideration pursuant to 37 CFR 1.142 (b) as being

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drawn to non-elected inventions. The withdrawn compounds and compositions contain varying functional groups which are chemically recognized to differ in structure, function, and reactivity. The scope of the invention is set in considering the elected species and the preferred embodiments. In addition, a reference, which anticipates one group, would not render obvious the other.

Therefore, claims 1-11, 13-23 and 30 will be examined on the merits.

### ***Specification***

The first paragraph of the specification does not contain continuing data to which the instant specification claims benefit from. An appropriate amendment is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 23 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The term "economy-class syndrome" is indefinite. It is not clear which diseases applicant refers to, and the specification fails to define such term.

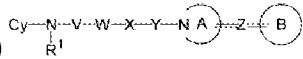
***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1-10, 13-14, 17, 19-23 and 30 are rejected under 35 U.S.C. §102(e) as being anticipated by Song et al., *U.S. Patent Application No. 11,298,317* (“the ‘317 application”, with effective filing date 12/07/2004 from the *Provisional U.S. Patent Application No. 60/634,201*).

Applicants’ claims relate to a compound of Formula (I) , or a prodrug thereof, wherein:

**Cy** is phenyl which may be substituted;

**R<sup>1</sup>** is a hydrogen atom;

**V** is –C(O)-;

**W** is –N(**R<sup>2</sup>**)-, wherein **R<sup>2</sup>** is a hydrogen;

**X** is alkylene which may be substituted;

**Y** is –C(O)-;

**Z** is a bond;

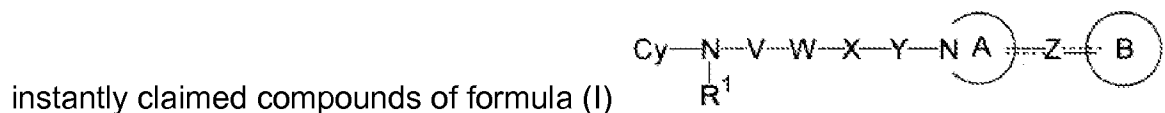
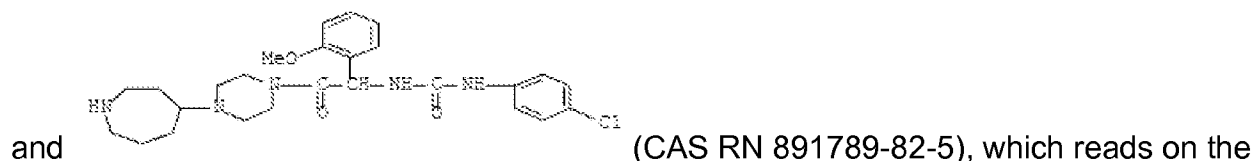
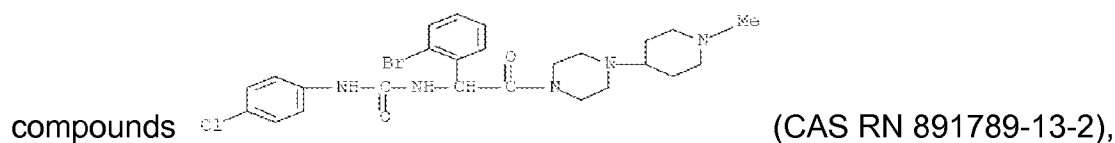
“-----” is a single bond,

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**Ring A** is a piperazine ring which may be substituted; and

**Ring B** is a nitrogen-containing heterocyclic group which may be substituted, or a pharmaceutical composition comprising said compound.

The instant claims 1-11, 13-14, 17, 19-23 and 30 are anticipated by the



wherein:

**Cy** is phenyl; **R<sup>1</sup>** is a hydrogen atom; **V** is  $-\text{C}(\text{O})-$ ; **W** is  $-\text{N}(\text{R}^2)-$ , wherein **R<sup>2</sup>** is a hydrogen; **X** is alkylene which may be substituted; **Y** is  $-\text{C}(\text{O})-$ ; **Z** is a bond;

“----” is a single bond,

**Ring A** is a piperazine ring which may be substituted; and

**Ring B** is a monocyclic nitrogen-containing heterocyclic group which may be substituted, or a pharmaceutical composition

The prodrug of formula (I) of claim 2 is also anticipated by the prior art teachings, because the prodrug is defined as the compound with alkylated amino group, which is anticipated by the cited compound (CAS RN 891789-13-2).



Claim 2 is also anticipated by the prior art teachings, because the amino acid residue in  $-W-X-Y-$  may be any divalent group that is obtained by eliminating one hydrogen atom and a hydroxyl radical from the amino group (unsubstituted amino group or N-monosubstituted amino group) and the carboxyl group, respectively, which constituted the amino acid, according to paragraph [0109] of the instant specification. Both cited prior art compounds are the residue of Tyrosine or Phenylalanine. Therefore, claim 11 is anticipated by the prior art teachings.

### ***Claim Rejections - 35 USC § 103***

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

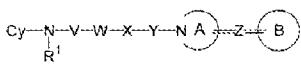
The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-11, 13-15, 17, 19-23 and 30 are rejected under 35 U.S.C. 103 (a) as unpatentable over the '317 application.

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Applicant's instantly elected invention of claims 1-10, 13-14, 17, 19-23 and 30

are related to a compound of Formula (I) , or a prodrug thereof,

wherein:

**Cy** is phenyl which may be substituted;

**R<sup>1</sup>** is a hydrogen atom;

**V** is  $\text{-C(O)-}$ ;

**W** is  $\text{-N(R}^2\text{)-}$ , wherein **R<sup>2</sup>** is a hydrogen;

**X** is alkylene which may be substituted;

**Y** is  $\text{-C(O)-}$ ;

**Z** is a bond;

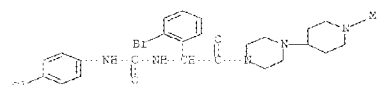
"-----" is a single bond,

**Ring A** is a piperazine ring which may be substituted; and

**Ring B** is a nitrogen-containing heterocyclic group which may be substituted, wherein the ring B is a fused nitrogen-containing heterocyclic ring, or a pharmaceutical composition comprising said compound.

Determination of the scope and content of the prior art (MPEP §2141.01)

The '317 application discloses a specific compound



and a pharmaceutical composition comprising the compound thereof.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

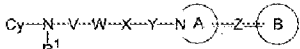
The difference between the cited prior art compound and the instantly claimed compounds is that **X** is alkylene for the instantly claimed compounds, and **X** is methylene group for the prior art compound.

*Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)*

The instantly claimed compounds would have been obvious over the prior art compound, because methylene is a homolog of alkylene. One skilled in the art would have been motivated to prepare homologue compound from the prior art teachings. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. as pharmaceutical application). Therefore, the instantly claimed compounds would have been suggested to one skilled in the art.

Claim 15 is rejected under 35 U.S.C. 103 (a) as unpatentable over the '317 application.

Applicant's instantly elected invention of claim 15 is related to a compound of

Formula (I) , or a prodrug thereof, wherein:

**Cy** is phenyl which may be substituted;

**R<sup>1</sup>** is a hydrogen atom;

**V** is -C(O)-;

**W** is -N(**R<sup>2</sup>**)-, wherein **R<sup>2</sup>** is a hydrogen;

**X** is alkylene which may be substituted;

**Y** is -C(O)-;

**Z** is a bond;

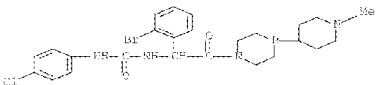
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“-----” is a single bond,

**Ring A** is a piperazine ring which may be substituted; and

**Ring B** is a nitrogen-containing heterocyclic group which may be substituted, wherein the ring B is a fused nitrogen-containing heterocyclic ring, or a pharmaceutical composition comprising said compound.

Determination of the scope and content of the prior art (MPEP §2141.01)

The '317 application discloses a specific compound , and a pharmaceutical composition comprising the compound thereof.

Ascertainment of the difference between the prior art and the claims (MPEP §2141.02)

The difference between the cited prior art compound and the instantly claimed compounds is non-fused monoheterocyclic N-methyl piperidine ring for the prior art and a fused nitrogen-containing heterocyclic ring for the instant claim.

Finding of prima facie obviousness--rational and motivation (MPEP §2142-2413)

The instantly claimed compounds would have been obvious over the prior art compound, because the prior art further teaches **ring B** can be fused-heterobicyclic group as “group A” in claim 38 of the '317 application. One skilled in the art would have been motivated to prepare fused-heterobicyclic compound from the teaching of the mono-heterobicyclic compound. The motivation to make the claimed compounds derives from the expectation that structurally similar compounds would possess similar activity (i.e. as pharmaceutical application). Therefore, the instantly claimed compounds would have been suggested to one skilled in the art.

### ***Claim Objections***

Claim 16 is objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Claims 20-23 are objected to under 37CFR 1.75 as being a substantial duplicate of claim 19. Recitation of an intended to use or utility in the preamble which can otherwise stand alone is not considered a further limitation of the claim and therefore cannot impart patentability to a known composition of matter. See, *in re Spada*, 15 USPQ.2d 1655 (Fed. Cir. 1990). When two claims in an application are duplicates or else are so close in content that they both cover the same thing, despite a slight difference in wording, it is proper after allowing one claim to object to the other as being a substantial duplicate of the allowed claim. See MPEP § 706.03(k). Applicants can overcome this objection by deleting claims 20-23.

Claims 1-11, 13-17, 19-23, and 30 are objected to for containing elected and non-elected subject matter. The elected subject matter has been identified *supra*.

### ***Conclusion***

- Claim 18 is allowed.
- Claims 1-11, 13-17, 19-23, and 30 are objected to.
- Claims 1-11, 13-15, 17, 19-23 and 30 are rejected.
- Specification is objected to.

***Telephone Inquiry***

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Yong Chu whose telephone number is 571-272-5759. The examiner can normally be reached between 7:00 am - 3:30 pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on 571-272-0699. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Status Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Yong Chu, Ph.D./  
Patent Examiner  
Art Unit 1626